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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/501,030	08/12/2004	Norbert E. Fusenig	0471-0286PUS1	3120

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EXAMINER

HENRY, MICHAEL C

ART UNIT	PAPER NUMBER
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1623

DATE MAILED: 06/26/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/501,030

Applicant(s)

FUSENIG ET AL.

Examiner

Michael C. Henry

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-17 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>7/7/04 & 4/11/05</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-9, 12-14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 15 and 17 recite the limitation "biomaterial". However, there is insufficient antecedent basis for this limitation in the claim. More specifically, there is no previous reference to the term "biomaterial" in the claims or in the claims on which claims 15 or 17 depends.

Claim 1 provides for "the use of benzyl ester of hyaluronic acid or a cross-linked derivative of hyaluronic acid....." but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced. Claims 2-9 and 12-14 which also provides for the "use of" are also encompassed by this rejection.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-9, 12-14 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a

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process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 10, 11, 15-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pavesio et al. (US 6,872,819 B1).

In claim 10, applicant claims "A method for the treatment and care of primary and secondary tumors which comprises filling a cavity resulting from the surgical removal of a tumor with a benzyl ester of hyaluronic acid or a cross-linked derivative of hyaluronic acid wherein the carboxy groups of hyaluronic acid are cross-linked to the hydroxyl group of the same or different hyaluronic acid molecule." Claims 11, 15-17 are drawn to said method wherein the hyaluronic acid is in association with other natural, synthetic and/or semisynthetic biopolymers, pharmacologically active substance, specific pharmacological active substance, and specific forms of the biomaterial.

Pavesio et al. disclose a method for regenerating in vivo mammal tissue comprising applying in vivo to the site requiring such a treatment a biocompatible biomaterial containing hyaluronic acid derivative of esters of hyaluronic acid wherein the hyaluronic acid derivative is hyaluronic acid partial ester with benzyl (a benzyl ester of hyaluronic acid) (see claims 1-7).

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Furthermore, Pavesio et al. disclose that said biocompatible biomaterial can further comprises at least another biocompatible natural, semisynthetic and/or synthetic polymer, can further contain pharmaceutically or biologically active substances and that the biocompatible biomaterial can further contains the non-woven fabrics (see claims 1-7). In addition, Pavesio et al. disclose that hyaluronic acid plays a vital role in many biological processes such as tissue hydration, proteoglycan organisation, cell differentiation, proliferation and angiogenesis, the facilitation of the tissue repair process, especially in the first stages of granulation, stabilising the coagulation matrix and controlling its degradation, favouring the recruitment of inflammatory cells such as fibroblasts and endothelial cells and, lastly, orienting the subsequent migration of the epithelial cells and that hyaluronic acid solutions can accelerate healing in patients affected by sores, wounds and burns. Also, Prevesio et al. disclose that hyaluronic acid derivatives maintain all the properties of the abovesaid glycosaminoglycan with the advantage of being processable in various forms and having adaptable solubility and degradation times according to the type and percentage of the derivation (col. 1, line 37-col.2, line 2).

The difference between applicant's claimed method and the method disclosed by Pavesio et al. is that Pavesio et al. do not exemplify the use of the hyaluronic acid benzyl ester to treat tumors by filling a cavity resulting from the surgical removal of a tumor. However, Pavesio et al. teach that hyaluronic acid benzyl ester can be applied to a site requiring regeneration of mammal tissue. This implies that said hyaluronic benzyl esters can be applied to any site that needs regeneration of tissue such as a cavity (site) resulting from the surgical removal of a tumor.

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It would have been obvious to one having ordinary skill in the art, at the time the claimed invention was made, in view of Pavesio et al. to treat tumors such as primary or secondary tumors by applying hyaluronic acid benzyl esters to any site that needs regeneration of tissue such as a cavity (site) resulting from the surgical removal of a tumor, since Pavesio et al. disclose that hyaluronic benzyl esters can be used to regenerate mammalian tissue.

One having ordinary skill in the art would have been motivated in view of Pavesio et al. to treat tumors such as primary or secondary tumors by applying hyaluronic acid benzyl esters to any site that needs regeneration of tissue such as a cavity (site) resulting from the surgical removal of a tumor, since Pavesio et al. disclose that hyaluronic benzyl esters can be used to regenerate mammalian tissue.

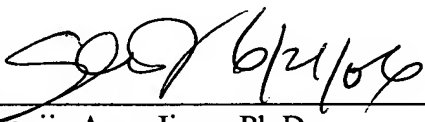
Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael C. Henry whose telephone number is 571-272-0652. The examiner can normally be reached on 8.30am-5pm; Mon-Fri. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia A. Jiang can be reached on 571-272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Michael C. Henry



Shaojia Anna Jiang, Ph.D.
Supervisory Patent Examiner
Art Unit 1623

June 21, 2006.